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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/341,079

Applicant(s)

FRESCO ET AL

Examiner

Stephen C Siu

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 3 and 18 is/are allowed.
- 6) ☐ Claim(s) 1,2,4-17 and 19-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

This Action is in response to Applicant's amendment and Declaration received September 29, 2000 (paper number 6).

The rejection of claims 1, 14, 16, and 29 under 35 U.S.C. 102(a) as being anticipated by Kim et al as cited in the Action mailed April 24, 2000 (paper number 4) is withdrawn after careful consideration of Applicant's arguments.

The rejection of claims 1-32 under 35 U.S.C. 112, second paragraph as cited in the Action mailed April 24, 2000 (paper number 4) is withdrawn in view of Applicant's amendments and arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 6, 14, 16, 21, 29, 31 and 32 under 35 U.S.C. 102(a) as being anticipated by Robles (J Am Chem Soc, 1996, Vol.118, No.24, pages 5820-5821) as cited in the office Action mailed April 24, 2000 (paper number 4) is maintained. Applicant's arguments filed September 29, 2000 (paper number 6) have been fully considered but they are not persuasive. Applicant states that the present invention stabilizes triplex DNA using water structure-making substances such as poly(ethylene

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glycol) and Robles uses hexa(ethylene glycol). Page 3 of the Amendment. Applicant further asserts that the glycol as used by Robles differs from the present invention in that the glycol used by Robles stabilizes third strand binding by virtue of minor groove insertion. Applicant's assertions of the alleged differences in the mechanism of stabilization are inapposite because the elements taught by Robles are the same as those of the claimed invention. The mechanism of action is not recited in the present claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Robles demonstrates the linking of the water structure-making substance to the third strand.

The rejection of claims 1-2, 4-5, 14, 16-17, 19-20 and 29 under 35 U.S.C. 102(b) as being anticipated by Kiyama (Nucleic Acids Research, 1995 FEB 11, Vol.23, No.3, pages 452-8) as cited in the office Action mailed April 24, 2000 (paper number 4) is maintained. Applicant's arguments filed September 29, 2000 (paper number 6) have been fully considered but they are not persuasive. Kiyama teaches the formation of triplex DNA structures and protection from degradation and stabilization of the triplexes in the presence of a cationic detergent, cetyltrimethylammonium bromide. Applicant states that the mechanism of triplex stabilization as disclosed by Kiyama could possibly be due to "other mechanisms", proposes possible alternative mechanisms, asserts that

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stabilization is not due to "water structure-making activities", and concludes that the teachings of Kiyama allegedly differ from the claimed invention (page 4 of the Amendment). However, the cited claims recite a method for triplex stabilization comprising addition of a "water structure-making substance" defined as any number of organic cations, cationic lipids, organic anions, inorganic anions, organic solvents, etc. Thus, the teachings of Kiyama contain each and every element as recited in the claimed invention. Kiyama teaches that the efficiency of protection is enhanced in the presence of a cationic detergent, cetyltrimethylammonium bromide, during triplex formation which anticipates the claimed invention.

The rejection of claims 1, 11-14, 16 and 26-29 under 35 U.S.C. 102(b) as being anticipated by D'Souza et al (Bioorganic and Medicinal Chemistry Letters, 1994, Vol.4, No.8, pages 965-70) as cited in the Office Action mailed April 24, 2000 (paper number 4) is maintained.

Claims 7, 9-10, 22 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Souza et al (Bioorganic and Medicinal Chemistry Letters, 1994, Vol.4, No.8, pages 965-70).

Applicant's arguments filed September 29, 2000 (paper number 6) have been fully considered but they are not persuasive. Applicant states that D'Souza allegedly uses ethanol in the destabilization of triplex formation. However, D'Souza teaches that "Ethanol is known to increase the stability of the complexation of a T15 third strand with duplex DNA in termolecular triple helices" and further teaches "the stabilization has

been attributed to the fact that B-form duplex DNA changes conformation to the A form at high ethanol concentrations;... added ethanol favors the triplex by stabilizing this conformation." (page 967, last paragraph). Thus, contrary to Applicant's assertions, D'Souza teaches the use of ethanol to stabilize triplexes. Further, D'Souza teaches organic anions in the buffer, e.g. MES, BES, CHES, and NaPO_4 (page 966).

The rejection of claims 1, 14-16, and 29-30 under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (Biochemistry, 18 Jan 1994 Vol.33, No.2, pages 606-13) as cited in the Office Action mailed April 24, 2000 (paper number 4) is maintained.

Claims 7-9 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (Biochemistry, 18 Jan 1994, Vol.33, No.2, pages 606-13).

Applicant's arguments filed September 29, 2000 (paper number 6) have been fully considered but they are not persuasive. The claims are drawn to a method for triplex stabilization using a base analog. Shimizu teaches a method of triplex stabilization wherein triplexes containing base analogs are examined in 1M NaCl (a "water structure-making substance" in that it is a substance that dissolves in water to yield ions which interact with water). Introduction of base analogs into triplex-forming oligonucleotides and subsequent examination of stability of the triplexes indicated increased cleavage yields which reflected higher thermal stability of triplexes formed (see abstract). Further, Shimizu teaches triplex stabilization to obtain thermal denaturation profiles performed in a buffer containing 100 mM sodium acetate – i.e., an organic ion (page 608, col.1, last paragraph). Applicant asserts that the triplex

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stabilization effects of Shimizu are allegedly not related to water structure-making ability of the solution additives however, this argument is not persuasive because triplex stabilization as per the teachings of Shimizu is effected in the presence of a water structure-making substance. Applicant further maintains that the base analogs of Shimizu did not significantly enhance triplex stability over triplexes formed using canonical bases. However, Shimizu reports increase stability of triplexes formed (see abstract) and thus anticipates the claimed invention.

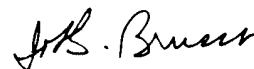
Conclusion

Claims 1-2, 4-17, 19-32. Claims 3 and 18 are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu



JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER